

B/C 1. (Once Amended) A hydrogel comprising less than 3.5% polyacrylamide by weight, based on the total weight of the hydrogel, said hydrogel obtainable by combining acrylamide and methylene bis-acrylamide, under conditions of radical initiation, and washing with pyrogen-free water or saline solution; said hydrogel being biocompatible.

B 5. (Once Amended) A hydrogel according to claim 2, comprising at least 0.5% by weight polyacrylamide, based on the total weight of the hydrogel.

6. (Once Amended) A hydrogel according to claim 2, which has complex viscosity not less than 2 Pas.

7. (Once Amended) A hydrogel according to claim 2, which has complex viscosity from about 2 to 90 Pas.

8. (Once Amended) A hydrogel according to claim 2, which has elasticity module of not less than 10 Pa.

9. (Once Amended) A hydrogel according to claim 2, which has elasticity module from about 10 to 700 Pa.

10. (Once Amended) A hydrogel according to claim 2, which includes the cross-linked polyacrylamide to such a degree so as to have an efficient cross-linking density of about 0.2 to 0.5%.

11. (Once Amended) A hydrogel according to claim 1, wherein the acrylamide and methylene bis-acrylamide are combined in the molar ratio of from 175:1 to 800:1.

12. (Once Amended) A hydrogel according to claim 3, wherein the implantable endoprosthesis comprises a silicone-based envelope housing the hydrogel.

B/D 15. (Once Amended) An endoprosthesis according to claim 13 further comprising cells.

16. (Once Amended) A method for the preparation of a hydrogel comprising the steps of combining acrylamide and methylene bis-acrylamide, under conditions of radical initiation, and washing with pyrogen-free water so as to give less than 3.5% by weight polyacrylamide, based on the total weight of the polyacrylamide.

B10  
17. (Once Amended) The method according to claim 16, wherein the hydrogel comprises at least 1.5% polyacrylamide by weight, based on the total weight of the hydrogel.

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B11  
19. (Once Amended) The method according to claim 16, wherein the washing step comprises swelling the product of the radical initiation step until the elasticity module is from about 10 to 700 Pa.

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20. (Once Amended) The method according to claim 16, wherein the washing step comprises swelling the product for 50 to 250 hours.

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B12  
22. (Once Amended) The method according to claim 21, wherein the ratio of acrylamide to methylene bis-acrylamide is about 175:1 to 800:1.

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23. (Once Amended) A method of treatment of a cosmetic or functional defect with an injectable or implantable biocompatible endoprosthesis comprising:

a) preparing a polyacrylamide hydrogel, said polyacrylamide hydrogel comprising less than 3.5% by weight of polyacrylamide and said polyacrylamide being cross-linked with methylene bis-acrylamide,

b) injecting or implanting a sufficient amount of said polyacrylamide hydrogel into a region of the body affected by a cosmetic or functional defect.

24. (Once Amended) The method of treatment according to claim 23, wherein the polyacrylamide hydrogel comprises at least 0.5% polyacrylamide by weight, based on the total mass of the hydrogel.

25. (Once Amended) The method according to claim 23, wherein the preparation of the polyacrylamide hydrogel is according to the method defined in claim 16.

26. (Once Amended) The method according to claim 23, wherein the endoprosthesis is used for mammoplastic reconstruction or augmentation, treating reflux oesophagitis, body contouring, or penis enlargement.

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B13  
28. (Once Amended) The method according to claim 26, wherein the hydrogel comprises less than 1.6% polyacrylamide by weight, based on the total weight

23  
of the hydrogel, and wherein the endoprosthesis for mammaplastic reconstruction is implantable, said endoprosthesis further comprising a silicone-based envelope.

29. (Once Amended) The method according to claim 23, wherein the polyacrylamide hydrogel comprises at least 1% by weight polyacrylamide, based on the total weight of the hydrogel.

30. (Once Amended) A method of cosmetically altering a mammalian breast or of performing a partial or total mammaplastic reconstruction on a woman comprising implanting a polyacrylamide hydrogel endoprosthesis; wherein said polyacrylamide hydrogel endoprosthesis comprises: i) more than 9.5% polyacrylamide by weight, based on the total weight of the hydrogel, and ii) at least 75% pyrogen-free water or saline solution.

31. (Once Amended) The method according to claim 30, wherein the polyacrylamide hydrogel endoprosthesis comprises less than 25% by weight polyacrylamide, based on the total weight of the hydrogel.

33. (Once Amended) A method according to claim 23 comprising augmenting the size of a penis comprising the administration to the penis of a polyacrylamide hydrogel, wherein the polyacrylamide hydrogel comprises less than 3.5% polyacrylamide by weight, based on the total weight of the hydrogel.

34. (Once Amended) The method according to claim 33, wherein the polyacrylamide hydrogel further comprises at least 95% pyrogen-free water or saline solution.

35. (Once Amended) The method according to claim 33, wherein the administration is by means of injection into a cavernous tissue.

36. (Once Amended) A method of augmenting the size of a penis comprising the implantation of a polyacrylamide hydrogel endoprosthesis wherein the polyacrylamide hydrogel endoprosthesis comprises i) more than 9.5% polyacrylamide by weight, and ii) pyrogen-free water or saline solution.

37. (Once Amended) The method according to claim 36, wherein the polyacrylamide hydrogel endoprosthesis has a complex viscosity of at least 10 Pa s.

B14  
38. (Once Amended) A method of cosmetically altering a mammalian body (body contouring) comprising implanting a polyacrylamide hydrogel endoprosthesis, wherein the polyacrylamide hydrogel endoprosthesis comprises i) more than 9.5% polyacrylamide by weight, based on the total weight of the hydrogel, and ii) pyrogen-free water or saline solution.

Please add new claims 41-43 as follows:

B15  
41. A hydrogel according to claim 1, wherein the acrylamide and methylene bis-acrylamide are combined in a molar ratio of 150:1 to 1000:1.

42. An endoprosthesis according to claim 15, wherein the cells are stem cells.

43. An endoprosthesis according to claim 15, wherein the cells are used for cellular engraftment.

#### REMARKS

##### **I. SPECIFICATION IS AMENDED TO CORRECT MINOR ERRORS.**

Applicants amended their specification to correct minor typographical and grammatical errors.

##### **II. CLAIMS HAVE BEEN AMENDED TO PLACE THEM IN A FORMAT PREFERRED IN U.S. PRACTICE. NEW CLAIMS ARE DIRECTED TO ADDITIONAL DETAILS OF INVENTION.**

Some claims have been amended to place them in a format preferred in U.S. patent practice. All amendments are supported by the specification, considered as a whole, and no impermissible new matter has been added.

Applicants also added new claims directed to additional details of the invention, support therefor also being found in the specification as filed, considered as a whole.